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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT	PAPER NUMBER
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DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/360,242

Applicant(s)

MCDONALD ET AL

Examiner

Robert Landsman

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 June 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-29, 31, 32, 34-38, 40, 42, 44-46, 48-54, 57 and 65-87 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-29, 31, 32, 34-38, 40, 42, 44-46, 48-54, 57 and 65-87 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 20, 21, 26
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Withdraw of Finality

A. The Office Action of 12/20/00 was made FINAL. However, upon further review of the issues and the arguments in this case, finality has been withdrawn and prosecution on the merits of this case continues.

2. Formal Matters

- A. The Change of Address, files 8/10/01, has been entered into the record.
- B. Claims 26-29, 31-32, 34-38, 40, 42, 44-46, 48-54, 57 and 65-87 are pending in the application.
- C. The Office Action dated 12/20/00 was made FINAL. However, in view of Applicants' arguments to that Action, prosecution has been reopened and the following rejections reinstated.
- D. All 35 USC Statutes not found in this Office Action can be found, cited in full, in a previous Office Action.

Withdrawn Claim Rejections

1. Claim Rejections - 35 USC § 112, first paragraph - enablement

A. All rejections under 35 USC 112, first paragraph, has been withdrawn in view of Applicants' arguments to the claims that the instant invention is enabled for the use of conjugates to treat pathological conditions by treating the underlying pathology associated with inflammatory responses. This is substantiated in Table 3 of page 15 of Applicants' response of Paper No. 25 which shows that numerous types of immune diseases can be treated by ligand-toxin fusion proteins.

2. Claim Rejections - 35 USC § 112, second paragraph

A. The rejection of claims 65, 68, 69 and 71 under 35 USC 112, first paragraph, has been withdrawn in view of Applicants amending the claims to recite a "chemokine receptor targeting agent."

New Claim Rejections

1. Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

A. Claims 26-29, 31-32, 34-38, 40, 42, 44-46, 48-54, 57 and 65-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogata et al. in view of Volk et al. and further in view of Applicants' admission on the record seen on Table 3 on page 15 of Applicants' response of Paper No. 25.

The claims teach a method of treating disorder associated with inflammatory responses by using a chemokine receptor targeting agent linked to a targeted agent. Ogata et al. teach the production of a targeting agent (cytokine – IL4) linked to a targeted agent (toxin). This is seen in Figure 1B. Ogata et al. do not teach the use of this conjugate in treating disorders. However, Volk et al. teach do teach a method of treating an inflammatory response by use of a conjugate comprising a chemokine targeting agent and a targeted agent (IL2-PE40).

Finally, Applicants' admit on the record as seen on Table 3 on page 15 of Applicants' response of Paper No. 25 that ligand-toxin fusion proteins which target immune disorders, such as lymphoma, leukemia, lymphoma and the general category of autoimmune diseases already exist. Therefore, it would have been obvious to one of ordinary skill in the art to use the conjugate of Ogata et al. as taught by Volk et al. since, it is well known in the art that various cytokines are involved in the modulation of the inflammatory response by stimulating and/or inhibiting immune effector cells and that "fusion conjugates" using non-chemokine cytokines are useful to treat inflammatory disorders. In addition, it would be obvious to one of ordinary skill in the art to produce these ligand-toxin fusion proteins as taught

Art Unit: 1647

by Applicants' admission on the record since these conjugates *already exist* to treat pathological immune conditions. The only key factor to the method of the instant invention is to select a ligand that specifically targets receptors on leukocytes, which should be readily obvious to one of ordinary skill in the art. Once a ligand has been targeted, all that needs to be done would be to conjugate a toxin to said ligand wherein the toxin would inhibit a biological function of the target cell.

For this reason, one of ordinary skill in the art would have been motivated to use the conjugate of Ogata et al. in the method of Volk et al. and as further taught by Applicants' admission since, once the concept and use of ligand-toxin conjugates already existed, it would have been readily expected that adapting this method of treatment to other disorders, especially those involving the immune system, as seen on page 15 of Paper No. 25, would be successful since all these treatments target cells.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
August 21, 2001

Gary L. Kunz
GARY L. KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER